REMARKS

Restriction Requirement

In the Office Action dated February 11, 2003, Examiner Davis imposed a restriction requirement under 35 U.S.C. §121 against claims 1-19 and required that an election be made between one of the following groups:

Groups 1-6, claims 1-5, drawn to a polypeptide that modulates programmed cell death, comprising SEQ ID NO: 1, 2, 3, 4, 5 or 8 classified in class 530, subclass 350. The Examiner contends that each polypeptide constitutes a single invention.

Groups 7-12, claims 6-8 and 18, drawn to a method for treating or preventing a disorder which is Alzheimer's disease, comprising administering a polypeptide that modulates programmed cell death, comprising SEQ ID NO: 1, 2, 3, 4, 5 or 8, classified in class 514, subclass 2. The Examiner contends that a method using each polypeptide constitutes a single invention.

Groups 13-18, claims 6-8 and 18 drawn to a method for treating or preventing a disorder which is cancer, comprising administering a polypeptide that modulates programmed cell death, comprising SEQ ID NO: 1, 2, 3, 4, 5 or 8, classified in class 514, subclass 2. The Examiner contends that a method using each polypeptide constitutes a single invention.

Groups 19-24, claims 6-8 and 18 drawn to a method for treating or preventing a disorder which is Parkinson's disease, comprising administering a polypeptide that modulates programmed cell death, comprising SEQ ID NO: 1, 2, 3, 4, 5 or 8, classified in class 514, subclass 2. The Examiner contends that a method using each polypeptide constitutes a single invention.

Groups 25-30, claims 6-8 and 18, drawn to a method for treating or preventing a disorder which is rheumatoid arthritis, comprising administering a polypeptide that modulates programmed cell death, comprising SEQ ID NO: 1, 2, 3, 4, 5 or 8, classified in class 514, subclass 2. The Examiner contends that a method using each polypeptide constitutes a single invention.

Groups 31-36, claims 6-8 and 18, drawn to a method for treating or preventing a disorder which is chronic or acute inflammation, comprising administering a polypeptide that modulates programmed cell death, comprising SEQ ID NO: 1, 2, 3, 4, 5 or 8, classified in class 514, subclass 2. The Examiner

contends that a method using each polypeptide constitutes a single invention. Upon election of any of groups 31-36, further election of the patentably distinct species chronic or acute inflammation is required.

Groups 37-42, claims 6-8 and 18, drawn to a method for treating or preventing a disorder which is AIDs, comprising administering a polypeptide that modulates programmed cell death, comprising SEQ ID NO: 1, 2, 3, 4, 5 or 8, classified in class 514, subclass 2. The Examiner contends that a method using each polypeptide constitutes a single invention.

Groups 43-48, claims 6-8 and 18, drawn to a method for treating or preventing a disorder which is degenerative liver disease, comprising administering a polypeptide that modulates programmed cell death, comprising SEQ ID NO: 1, 2, 3, 4, 5 or 8, classified in class 514, subclass 2. The Examiner contends that a method using each polypeptide constitutes a single invention.

Groups 49-55, claims 9-11, 14-16 and 19, drawn to a polynucleotide encoding a polypeptide that modulates programmed cell death, comprising SEQ ID NO: 1, 2, 3, 4, 5 or 8, classified in class 536, subclass 23.1. The Examiner contends that each polypeptide constitutes a single invention.

Groups 56-61, claim 12, drawn to a method for detecting a polynucleotide encoding SEQ ID NO: 1, 2, 3, 4, 5 and 8, classified in class 435, subclass 6. The Examiner contends that a method using each polypeptide constitutes a single invention.

Groups 62-67, claim 13, drawn to a method for screening apoptosis inhibiting compounds, comprising contacting the test compound with a cell which expresses the protein of SEQ ID NO: 1, 2, 3, 4, 5 and 8, classified in class 435, subclass 7.1. The Examiner contends that a method using each polypeptide constitutes a single invention.

Groups 68-73, claim 17, drawn to an antibody that binds to the polypeptide of SEQ ID NO: 1, 2, 3, 4, 5 or 8, classified in class 530, subclass 387.1. The Examiner contends that an antibody which binds to each polypeptide constitutes a single invention.

Applicant traverses such a restriction requirement and questions whether the Office can really justify splitting the present application into **SEVENTY-THREE (73)** distinct and different patentable inventions.

Clearly, the product claims and method of using the products are not patentably distinct from each other because one having a method of using the instantly claimed polypeptides would obviously have to have the peptides to perform the method. Thus, the polypeptides are not patently distinct from the method of making and/or using the polypeptides. The interdependence of the polypeptide product claims and the method of use thereof is confirmed --indeed, it is mandated-- by virtue of the fact that the description requirements of 35 U.S.C. §112 compel disclosure of different aspects of the invention in the one application which applicants have filed.

In addition, the courts have recognized that it is in the public interest to permit an applicant to claim several aspects of his/her invention together in one application, as the applicant has done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved. *In re Kuehl,* 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973).

This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Office held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to an applicant against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that §121 protects a patentee from an allegation of same-invention double patenting, *Studiengesellschaft Kohle mbH v. Northern Petrochemical Co.,* 784 F.2d 351, 355, 228 U.S.P.Q. 837, 840 (Fed. Cir. 1986); and in *Gerber Garment Technology Inc. v. Lectra Systems Inc.*, 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990) that court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public's interest, the Office is not to require restriction in cases, such as the present application, wherein various aspects of a unitary invention are claimed.

To overcome the unnecessary cost of filing 72 additional applications, the MPEP Section 821.04 recites that when elected product claims are found to recite patentable subject matter then all method claims for making and/or using the products may be rejoined and examined in this one application provided the method of making and using claims recite the product found to be patentable during examination of the elected invention. Thus understood, applicant requests that when the product claims are found to recite patentable subject matter, non-elected method claims are to be rejoined and taken up for examination.

According to the Office, each of the disclosed "polypeptide constitutes a single invention." As such, the Office contends that SEQ ID NOs. 1- 5 and 8 are patentably distinct and thus will not be examined in one application. A review of the amino acids sequences of SEQ ID NO: 1-5 shows that the sequences are variants of each other with some minor substitutions, deletions, insertions and additions, however, all variants possess the same apoptotic activity and have a conserved carboxy end region. Even if the Office, contends that each sequence represents an independent and distinct invention, the Commissioner in 1996 partially waived the requirements of 37 CFR 1.141 and now permits a reasonable number of sequences to be claimed in a single application. Although the decision by the Commissioner related to distinct nucleotide sequences, his decision to allow up to ten sequences to be examined in one application is applicable to the present situation. His decision to waive the requirements of 37 CFR 1.141 was in response to a need in the biotechnology industry to protect its intellectual property without requiring the filing of 73 different applications, such as in this situation, while not creating undue burden on the Office. Clearly it is not an undue burden on the Office to run 6 amino acid sequences through a BLAST program offered free on the web.

In view of the addition of new claims 20 and 21, it is requested that the restriction requirement be reconsidered and restructured by the Office to consolidate Groups 1-6 into a single group that includes SEQ ID NOs. 1-5 and 8 for unitary examination and further prosecution. In the event the requirement is adhered to, applicant provisionally elects with traverse, the invention of Group 2 drawn to claims 1-5 which includes SEQ ID NO: 2, for further examination on the merits.

It is requested that all non-elected claims be held in abeyance and reconsidered for rejoinder upon finding of allowable subject matter relative to the elected claims, or alternatively, with reservation of the right to

file divisional application(s) directed to the subject matter of those claims that have been cancelled herein.

Resubmission of Sequence Listing

The sequence listings submitted on October 29, 2001 refer to Misc_Features at lines <220> through <223> for SEQ ID NO: 1, 2, 4, and 5, however, there is no miscellaneous features in SEQ ID NO: 1, 2, 4, and 5. Accordingly, applicant resubmits the sequence listings to rectify this error, including:

(1) a paper copy of the document entitled "Sequence Listing.ST25" ("Sequence Listing");

(2) a computer readable copy of the Sequence Listing recorded on February 27, 2003 and checked for errors using Checker Version 4.0 on February 27, 2003; and

(3) a statement under 37 C.F.R. §1.821 (f) for the Sequence Listing.

No new matter was added in the resubmission. The resubmission was sent under separate cover, via Federal Express, to Box Sequence, Crystal Plaza Two, Lobby Room 1B03, Arlington, Virginia 22202.

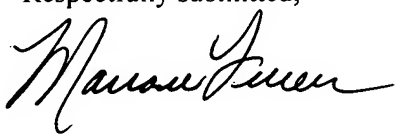
Fee Payable for Added Claims 20-25

The addition of new claims 20-25 herein increases the number of independent claims in the application by four in number, and the total number of claims by six in number. Accordingly, an added claims fee of $222.00 is required, and same is included in the check enclosed herewith in the amount of $222.00 payable to the Commissioner for Patents and Trademarks. Please charge any additional fee or amount properly payable in connection with the entry of this response, to Deposit Account No. 08-3284 of Intellectual Property/Technology Law.

CONCLUSION

It therefore is requested that examination and prosecution proceed on the merits, consistent with this Response. In the event that any issues remain, Examiner Davis is requested to contact the undersigned attorney at (919) 419-9350 to resolve same.

Respectfully submitted,



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